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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER CRAIG, PAULA L	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 10/06/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/582,214	Applicant(s) NEGRIER ET AL.	
	Examiner PAULA L. CRAIG	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The title of the application given on page 1 of the specification is not the same as the title indicated on the Application Data Sheet.
2. The use of the trademark Silkis has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology (such as calcitriol lotion). Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not teach the first compartment being able to contain a quantity of around 0.36g as required by Claim 10. Appropriate correction is required.

Drawings

4. The drawings are objected to under 37 CFR 1.84 (e) and 1.84(l), and 1.84(p) because of poor line quality in Figs. 1-3, in that the lines, numbers and letters are not uniformly thick and well defined, clean, and black; the numbers and reference

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characters are not all at least 0.32 cm in height; and numerous copy machine marks. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 14 is objected to because of the following informality: In Claim 14, line 1, "according claim" should be "according to claim". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-3, 5-8, 10-14, and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear to the Examiner whether or not the limitations following the term "preferably" are being claimed. In Claim 2, "the following compartments" lacks antecedent basis. In Claims 6 and 11, "the second" lacks antecedent basis. In Claims 7 and 12, "the second" and "the third" lack antecedent basis. In Claims 8 and 13, "the second", "the third", and "the fourth" or "fourth" lack antecedent basis. In Claim 15, "the graduation" lacks antecedent basis. In Claim 16, "the first" lacks antecedent basis.

8. Claims 10-13 and 20 contain the trademark/trade name Silkis. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the composition and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 9, 14-15, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,522,622 to Peery et al.

11. For Claim 1, Peery teaches a metering device for a product which is a pharmaceutical composition; the device is fully capable of being used with a product intended to be applied to the skin (Abstract, Figs. 1-6, col. 1, lines 5-11 and 31-38, col. 2, lines 34-68, col. 3, lines 44-60, col. 4, line 63 to col. 5, line 7, Claims 1, 7). Peery teaches an applicator stick 1 with a longitudinal groove along which is defined a series of compartments 3 (groove includes passageways 6; Figs. 1-2, col. 2, lines 34-68, Claim 1). The groove is fully capable of accommodating a quantity of composition corresponding to a defined surface area of the skin to be treated, with this quantity being defined by one or more compartments 3 (Figs. 1-2, col. 2, lines 34-68, col. 3, lines 13-44, Claim 1).

12. For Claim 2, Peery teaches the applicator stick 1 being fitted with graduations which from one end of the groove corresponding to the start of the first compartment and for the following compartments, define the quantity of composition in the compartments of the groove (Abstract, Figs. 1-2, col. 2, lines 34-68, col. 3, lines 13-44, Claim 1).

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13. For Claims 3 and 14, Peery teaches at least two compartments 3 (Figs. 1-2, col. 2, lines 34-68, Claim 1).

14. For Claims 4 and 15, Peery teaches the graduation of the applicator stick including protuberances and notches (Abstract, Figs. 1-2, col. 2, lines 34-68, col. 3, lines 13-44, Claim 1).

15. For Claims 9 and 20, the device of Peery is fully capable of containing a composition intended to treat psoriasis (Figs. 1-2 col. 1, lines 5-38, col. 2, lines 34-68, col. 3, lines 13-60, col. 4, line 63 to col. 5, line 7, Claims 1, 7; note that the composition itself is not claimed).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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17. Claims 5-8, 10-13, and 16-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Peery in view of U.S. Patent Application Publication No. 2004/0071494 to Staniforth et al.

18. For Claims 5-8 and 16-19, Peery teaches all the limitations of Claims 2, 3, and 4, as described above in paragraphs 12, 13, and 14 respectively. Peery teaches four compartments (Figs. 1-2, col. 2, lines 34-68). Peery teaches each compartment of the device containing a quantity of the composition for a unit dose (col. 1, lines 5-11, 31-38, col. 2, lines 34-68, col. 3, lines 13-60, col. 4, line 63 to col. 5, line 20, Claim 1). Peery does not expressly teach the first, second, third, or fourth compartment being able to contain a quantity of composition corresponding approximately to an area of the total surface of the body. The quantity of the composition dispensed by the device is a result effective variable, since it affects the dosage delivered. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980). Staniforth confirms this and teaches a metering device including compartments, with each compartment holding a suitable quantity of composition for application to the surface of a body (Figs. 1-21, paragraphs 2, 4-14, 15, 79-108, Claim 1). Staniforth teaches that it is desirable in the treatment of skin disorders for the dosing regime to be adhered to accurately (paragraphs 4-9, 15). Staniforth teaches application of a unit dose of a therapeutically effective amount of a therapeutic agent to the skin (paragraphs 26, 38, 44, 79-82, 103). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Peery to include each compartment being able to contain a suitable quantity

of the composition, as taught by Staniforth, to allow unit doses to be applied and a dosing regime to be adhered to accurately, as taught by Staniforth.

19. For Claims 10-13, Peery teaches all the limitations of Claim 9, as described above in paragraph 15. Peery teaches four compartments (Figs. 1-2, col. 2, lines 34-68). Peery teaches each compartment of the device containing a quantity of the composition for a unit dose (col. 1, lines 5-11, 31-38, col. 2, lines 34-68, col. 3, lines 13-60, col. 4, line 63 to col. 5, line 20, Claim 1). Peery does not expressly teach the first, second, third, or fourth compartment being able to contain a quantity of around 0.36 g to 0.54 g, 1.08 g to 1.62g, 2.16 g to 3.20 g, or 3.24 g to 4.86 g of Silkis. The quantity of the composition held in each compartment of the device is a result effective variable, since it affects the dosage delivered. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. Staniforth confirms this and teaches a metering device including compartments, with each compartment holding a suitable quantity of composition for a unit dose (Figs. 1-21, paragraphs 2, 4-14, 15, 26, 38, 44, 79-108, Claim 1). Staniforth teaches application of a unit dose of a therapeutically effective amount of a therapeutic agent to the skin (paragraphs 26, 38, 44, 79-82, 103). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Peery to include each compartment being able to contain a suitable quantity of the composition, as taught by Staniforth, to allow unit doses to be applied and a dosing regime to be adhered to accurately, as taught by Staniforth.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA L. CRAIG whose telephone number is (571)272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paula L Craig
Examiner
Art Unit 3761

/P. L. C./

/Tatyana Zalukaeva/

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Supervisory Patent Examiner, Art Unit 3761